REMARKS

Applicants express appreciation to the Examiner for the in-person interview granted to applicants' representatives. As presented herein for reconsideration, the claims have been amended as proposed. Specifically, claims 17, 36, 50, and 52 have been amended.[1] Thus, by this paper, claims 17, 36-44, 50, and 52-59 remain pending, of which claims 17, 36, and 50 are the independent claims.

Vascular closure devices are used to facilitate closure of a puncture site in a body lumen. A puncture site may be closed by bringing the edges of the puncture together. Improved closure may be achieved by bringing both the edges and at least a portion of the internal surface of the body lumen together. Merely bringing the edges together may be insufficient in cases where the puncture site does not, for example, provide a symmetrical clean edge. Applicants have developed a closure device for engaging tissue at the puncture site in a way that provides more effective closure of the puncture site.

As presented herein for reconsideration, applicants' claimed invention comprises (see independent claim 17, as exemplary) a device for engaging tissue at a puncture site and facilitating closure of the puncture site. The device comprises an annular-shaped body that defines a plane and is disposed about a central axis extending substantially normal to the plane. The body includes a plurality of looped elements that extend about a periphery of the body to form an endless sinusoidal pattern. The device also comprises a plurality of tines having free distal ends extending from the looped elements towards the central axis of the generally annular-shaped body. The body and tines include a resilient material so that the body and tines normally lie in a planar, deployed first configuration. The material of the body and tines is sufficiently resilient so that when a force is applied to the tines they are forced from the planar, deployed first configuration into a transverse, pre-deployment second configuration in which the tines and free distal ends are spread open and generally extend in the direction of the central axis for insertion of the free distal ends into the tissue around the puncture site. Thereafter, the body and tines will

[1] Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

automatically return toward the first configuration so as to engage the puncture site and facilitate closure thereof after the force is removed.[2]

In the Office Action, independent claims 17, 36, and 50 were rejected as being obvious over U.S. Patent No. 5,907,893 (Zadno-Azizi) in view of U.S. Patent No. 6,942,691 (Chuter) or in view of U.S. Patent No. 5,843,167 (Dwyer).[3] As discussed in the interview, and as presented herein for reconsideration, independent claims 17, 36, and 50 and their depending claims are neither anticipated nor made obvious by Zadno-Azizi, Chuter, or Dwyer, either singly or in combination with any other prior art of record, and thus favorable reconsideration is respectfully requested.

Zadno-Azizi is concerned with methods for manufacturing radially expansible stents.[4] Specifically, Zadno-Azizi describes improved methods for fabricating cylindrical stents from planar articles that are patterned or formed in a planar configuration and reformed into a

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[2] Independent claims 36 and 50 are similar. Claims 36 differs from claim 17 by adding a further limitation that requires that the tines are "arcuate." Claim 50 differs from claim 17 by adding a further limitation that requires that the tines are "substantially straight."

[3] The dependent claims were rejected as obvious over Zadno-Azizi in view of Chuter, Dwyer, and/or Sakura. While the arguments herein are focused on the differences between the independent claims and the prior art of record, which differences are equally applicable to the dependent claims, this does not mean that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicants thus do not acquiesce in any asserted rejections of the dependent claims. Any assertion in the Office Action not expressly traversed as to any dependent claims is not intended to constitute, and should not be construed as, an acquiescence on the part of applicants as to the purported teachings or prior art status of the cited references, as to the characterization of the cited references advanced by the Examiner, or as to any other assertions, allegations or characterizations made by the Examiner. Applicants reserve the right to challenge the purported teaching of the cited references or any judicial notice asserted at any appropriate time.

[4] In that respect Zadno-Azizi is contrary in its intended purpose and use. A stent is used to keep a vessel such as a heart artery *open,* rather than to close tissue as in the case of applicants' claimed closure device. For this reason alone, the asserted rejection of the previously pending claims would seem improper as failing to have been grounded on a proper *prima facie* case. *See In re Clay*, 966 F.2d 656, 658-69 (Fed. Cir. 1992), noting that "A reference is not available to be used in a 103 rejection if it is not "analogous art," and further noting that "Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor [as the invention], and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." Here, the field of endeavor for the claimed invention is closure devices for closing subcutaneous punctures, whereas the field of endeavor addressed by Zadno-Azizi is stents for keeping blood vessels open. *See id.* at 659 (holding that art in the field of *extracting* petroleum was not analogous art for invention in the field of *storing* petroleum). Moreover, Zadno-Azizi is not reasonably pertinent to the particular problem solved by the invention. As noted above, the claimed invention is used to close subcutaneous punctures, whereas the device disclosed in the Zadno-Azizi is used to open blood vessels, something quite different.

Notwithstanding this point, as noted in the remarks applicants' claimed closure device is in any event patentable over the asserted references for the further reason that as presented herein, the claimed device is significantly different in its structure as well as its operation from that shown in the prior art of record, and as such, is neither anticipated nor made obvious by the prior either singly or in combination, even assuming such combination to be otherwise proper.

cylindrical wall. The reforming step includes bending the planar article to the desired final cylindrical configuration. During or subsequent to bending, the article may be treated to change certain physical properties by, for example, heat treating the article in order to reduce stress, change elasticity, change appearance, or the like. For shape memory alloys, it will usually be necessary to heat treat the article in order to provide the desired final shape. Accordingly, at best Zadno-Azizi describes using planar articles from which cylindrically-shaped or tapered stents are manufactured.

Even in the planar configuration before the stent is bent into its final cylindrical form, Zadno-Azizi does not teach a plurality of tines extending from the looped elements towards the central axis of the annular shaped body, as acknowledged in the Office Action. Thus, the Office Action then looks to Chuter as teaching the use of a plurality of tines.

Chuter is concerned with modular bifurcated grafts for endovascular aneurysm repair. Chuter identifies a need for an improved modular bifurcated graft that embodies robust junctions between modular elements. To achieve this need, Chuter utilizes various support structures to anchor the grafts against migration. In addition to the geometry of the support structures, hooks 58 (see Fig. 3) may be used to enhance the ability to attach the graft to the vascular wall if necessary and to prevent migration. In summary, Chuter's support structures are cylindrical structures designed to aid in grafting one vessel to the other, and thus to support a blood vessel. Like Zadno-Azizi, Chuter contains no teaching that relates to *closure* of a puncture site.

As will be appreciated, Zadno-Azizi's methods for manufacturing radially expansible stents and Chuter's modular bifurcated grafts for endovascular aneurysm repair are significantly different from the devices for engaging tissue at a puncture site and facilitating closure of the puncture site claimed by applicants, and does not teach or suggest a device having, *inter alia*, "the *body and tines comprising a resilient material so that the body and tines normally lie in a planar, deployed first configuration*, the material of the body and tines being sufficiently resilient *so that when a force is applied to the tines they are forced from the planar, deployed first configuration into a transverse, pre-deployment second configuration in which the tines are spread open and generally extend in the direction of the central axis*" (independent claims 17, 36 and 50, emphasis added), and ""hereafter, *the body and tines will automatically return toward*

the first configuration so as to engage the puncture site and facilitate closure thereof after the force is removed (independent claims 17, 36 and 50, emphasis added).[5]

As also discussed at the interview, applicants have submitted herewith a terminal disclaimer for related application SN10/390,586 which was also discussed at the interview. In addition, the Examiner was given detailed charts showing the information by serial number and filing date of all other applications related by filing date or subject matter to this application, and has agreed to review with the Examiner any other cases arising from those further applications which may necessitate terminal disclaimers to obviate obviousness-type double patenting issues.

There being no other rejections of record, and for at least the reasons noted, independent claims 17, 36 and 50 are patentable over the prior art of record. Indeed, as noted in the Interview Summary prepared by the Examiner at the interview's conclusion, proposed "amendment to Claim 17 overcomes the rejection of record . . . [and] similar amendments to the other independent claims will also be made to overcome the rejection of record." Thus, favorable reconsideration and allowance is respectfully requested.

In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

[5] The secondary references to Dwyer and Sakura were also briefly discussed at the interview, and it was acknowledged that these references were much less relevant than those discussed above, and add nothing beyond those references relating to the distinctions of the claims over the prior art, as noted. Similarly, Derowe was also discussed as noted in the Interview Summary. Derowe discloses a vascular port device designed to maintain the puncture site open in a first configuration, and then seal the puncture site in a second configuration. Various embodiments are shown, such a fig. 1J, in which the spikes are always maintained in a transverse position, and the ring304 contracts to pull the spikes 302 closer together. Other embodiments such as those shown in figs. 8C-8D also rely on a central ring which contracts and by doing so hooks the tissue with tines 354. This reference was also clearly acknowledged as distinguished by the claims presented herein.

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Respectfully submitted,

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